

WHAT IS CLAIMED IS:

- 864740-409060
1. A composition for delivering a biologically active agent, comprising: an emulsion or dispersion of a biologically active mixture and a controlled release formulation, the biologically active mixture comprising the biologically active agent and a pharmaceutically acceptable protective carrier; and the controlled release formulation comprising a pharmaceutically acceptable, biodegradable matrix forming material that is substantially insoluble in an aqueous or body fluid and a pharmaceutically acceptable organic solvent.
 2. A precomposition suitable for preparing a composition according to claim 1, comprising separate containers of the biologically active mixture and controlled release formulation, which containers are adapted to cause combination of the biologically active mixture and controlled release formulation.
 3. A composition of claim 1, wherein the biologically active agent is selected from the group consisting of an antiinflammatory agent, an antibacterial agent, an antifungal agent, an analgesic agent, an anesthetic agent, an immunogen, a vaccine, an antineoplastic agent, a growth or survival agent, a hormone, a cardiovascular agent, an anti-ulcer agent, a bronchial agent, a central nervous system agent, a gene, a gene fragment, an insertion vector carrying a gene or gene fragment, and any combination or multiple thereof.
 4. A composition of claim 1, wherein the protective carrier is a non-aqueous substance.
 5. A composition of claim 4 wherein the non-aqueous substance is a lipid substance.
 6. A composition of claim 5 wherein the lipid substance is a low-melting wax, oil, fat or lipid.
 7. A composition of claim 6 wherein the lipid substance is a plant oil.

8. A composition of claim 7 wherein the plant oil is selected from the group of oils consisting of sesame, soybean, castor, peanut, olive, arachis, maize, almond, corn, cottonseed, palm, flax, sunflower, cannoli, safflower, rape, coconut, babassu, and almond.
10. A composition of claim 6 wherein the lipid substance is a wax or fat selected from the group consisting of carnoba wax, beeswax, tallow, monoglyceride, diglyceride and triglyceride.
11. A composition of claim 1, wherein the protective carrier is an aqueous substance.
12. A composition of claim 1, wherein the matrix forming material is a thermoplastic polymer.
13. A composition of claim 12 where the thermoplastic polymer is biocompatible, biodegradable, bioerodible, and substantially insoluble in aqueous or body fluids.
14. A composition of claim 13 wherein the thermoplastic polymer formula contains monomeric units selected from the group consisting of lactide, glycolide, caprolactone, anhydride, amide, urethane, esteramide, orthoester, dioxanone, acetal, ketal, carbonate, phosphazene, hydroxybutyrate, hydroxyvalerate, alkylene oxalate, alkylene succinate, amino acid and any copolymer and terpolymer combination of these monomeric units in random order or in block order.
15. A composition of claim 14 wherein the monomeric units include lactide, glycolide, caprolactone, hydroxybutyrate, and any combination thereof.
16. A composition of claim 1, wherein the matrix forming material is a non-polymeric material.
17. A composition of claim 1, wherein the organic solvent has a high water solubility.
18. A composition of claim 1, wherein the organic solvent has a low water solubility.

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19. A composition of claim 1, wherein the emulsion is a water-in-oil emulsion.
20. A composition of claim 1, wherein the emulsion is an oil-in-oil emulsion.
21. A composition of claim 1, wherein the emulsion is a water-in oil-in oil emulsion.
22. A composition of claim 1, wherein the biologically active agent is encapsulated in a polymeric nanoparticle or microparticle.
23. A composition for delivering a biologically active agent, comprising: an emulsion or dispersion of a biologically active mixture and a controlled release formulation, the biologically active mixture comprising the biologically active agent and a pharmaceutically acceptable fat, oil or low melting wax acting as a protective carrier for the biologically active agent; and the controlled release formulation comprising a pharmaceutically acceptable, biodegradable, bioerodable thermoplastic polymer that is substantially insoluble in aqueous or body fluid, and a pharmaceutically acceptable organic solvent that is partially to completely soluble in the aqueous or body fluid.
24. A composition of claim 23 wherein the composition is an oil in oil emulsion, the pharmaceutically acceptable fat, oil or low melting wax is a plant oil; the pharmaceutically acceptable, biodegradable, bioerodable thermoplastic polymer comprises monomeric units of lactide, glycolide, caprolactone, or hydroxybutyrate, or any combination thereof, and the pharmaceutically acceptable organic solvent is ~~ethanol~~, N-methyl pyrrolidone, 2-pyrrolidone, ethyl acetate, dimethylsulfoxide, ethyl lactate, glycofurol, glycerol formal, isopropylidene glycol, propylene carbonate, triethyl citrate, isopropyl myristate, or glyceryl triacetate.
25. A method of sustained delivery of a biologically active agent to a patient, comprising:
 - (a) combining the biologically active mixture with a controlled release formulation to form a drug delivery composition as an emulsion or

dispersion, wherein the controlled release formulation comprises a pharmaceutically acceptable, biodegradable matrix forming material that is substantially insoluble in an aqueous or body fluid and a pharmaceutically acceptable organic solvent; and the biologically active mixture comprises a biologically active agent and a pharmaceutically acceptable protective carrier; and

- (b) administering an effective amount of the drug delivery composition to the patient.

26. The method of claim 25, wherein the biologically active agent is protected from dissolution by the controlled release composition.

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